## REMARKS

The 35 U.S.C. §112, first paragraph rejection

Claims 22-31 remain rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed.

The Examiner states that the Declaration submitted by Applicant does not enable the instant invention. The instant invention is directed to a vaccine, but Applicant's Declaration only shows that the peptides can induce an immune response. The Declaration does not show that the peptides have any protective effects.

Applicant respectfully contends that the Declaration provides sufficient evidence to enable one skilled in the art to vaccinate an individual against stratum corneum chymotryptic enzyme as claimed, without undue experimentation. The Declaration states that peptides having binding motifs for HLA class I molecules were tested directly for their ability to induce specific $CD8^+$ cytotoxic T lymphocyte responses from normal adult donors of monocyte-derived dendritic cells (page 1).

Mature dendritic cells loaded with peptide were able to stimulate $CD8^+$ cytotoxic lymphocyte responses in T cell lines; this effect is demonstrated to be specific to SCCE peptides (pages 2-3). Thus, the Declaration demonstrates that the peptides having binding motifs for HLA class I molecules are able to induce specific cytotoxic T lymphocyte responses. Further, the Declaration shows that the induced cytotoxic lymphocytes are able to recognize and kill targets that process and present endogenously expressed SCCE tumor antigens (page 4).

Applicant respectfully submits that the protective effect of the claimed vaccination method is demonstrated by the Declaration, in that the peptides are not only able to induce a specific cytotoxic T lymphocyte response, but that the induced lymphocytes recognize and kill target cells expressing and presenting SCCE antigen. Such effects correspond to important stages of the immune response that is known to occur upon invasion of the body by foreign antigens (*see* Voet, D.V. and Voet, J.G., *Biochemistry*, John Wiley & Sons, New York: 1990, pages 1096-1098). The purpose of vaccination is to provide an antigen against which the body will launch an immune response; subsequently, should the body be exposed to the antigen a second time, the immune system will "remember" the antigen and then quickly eliminate the cells

presenting the antigen, in order to prevent disease (*see Id.*, page 1098). If the specification describes a method of use for which the art recognizes standard modes of administration, it is not necessary to specify the method to satisfy 35 U.S.C. 112 (*see* M.P.E.P. §2164.01(c)). The Declaration successfully demonstrates the elements of the desired protective effect of the claimed vaccination method, which when combined with standard methods of vaccination that are known in the art, enables one skilled in the art to carry out the claimed invention without undue experimentation.

In addition, claims 26-31 are drawn to a method of producing immune-activated cells directed toward stratum corneum chymotryptic enzyme. The production of cytotoxic T lymphocytes by peptide-loaded dendritic cells from human donors, as described in the Declaration, provides a direct example of the claimed method. Therefore, Applicant respectfully submits that claims 26-31 are likewise enabled by the Declaration.

This is intended to be a complete response to the Final Office Action mailed March 19, 2003. If any issues remain outstanding, the

Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

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